Procter& Gamble SANITIZED

The Procter & Gamble Company Ivorydale Technical Center 5299 Spring Grove Avenue, Cincinnati, Ohio 45217-1087 92 AUG 31 PM 1: 16

8EHQ-0892-13387

Public Display Copy

August 20, 1992

Document Processing Center (TS-790)
Office of Toxic Substances
Environmental Protection Agency
401 M St. S.W.
Washington, D.C. 20460

Attn: Section 8(e) Coordinator (CAP Agreement)

454920011007 CAY

This submission is being made pursuant to the TSCA Section 8(e) Compliance Audit Program and the terms of CAP Agreement # 8ECAP-0003. This report discharges our Company obligation to report the attached data under TSCA Section 8(e). The filing of these studies does not indicate that we agree that "substantial risk" exists. We are following the agency's guidance and the terms of the CAP agreement, but we expressly disclaim that the filings reflect a decision that these materials pose any significant human or environmental safety risks.

The material identified in the attached report as K0316.01 is a confidential mixture. The composition of the mixture is appended as Attachment 1. The report is titled "Acute Oral Toxicity Study in Albino Rats with K0316.01". Any correspondence relating to this submission should reference study # 1201-27807.

The attached study report indicates oral administration of the test material resulted in pharmacotoxic signs including ataxia, lethargy, and inactivity following oral administration of 6.0 and 7.4 g/kg of the test material. No significant clinical signs were observed in groups dosed 3.2 and 4.6 g/kg. The acute oral LD50 was determined to be >7.4 g/kg.

We do not believe findings in this report reasonably support a conclusion of substantial risk to human health or the environment. Nevertheless, we are submitting this report to discharge any potential liability under TSCA Section 8(e).

To our knowledge, this report has not been the subject of a prior submission to EPA under the provisions of TSCA.

The specific chemical constituents and percentage composition of this mixture is claimed as confidential business information. A sanitized version of this submission containing generic chemical names has been included as part of this submission. Answers to the seven questions required to substantiate this claim of confidentiality are provided below:

- Confidentiality of the chemical constituents and their percentages should be maintained indefinitely. There are no plans for this information to be otherwise disclosed, and this technology has significant commercial value.
- 2. To our knowledge, there have been no government confidentiality determinations made for this mixture.
- 3. The specific chemical identity and exact proportions of the constituents of this mixture have not been disclosed outside the Company. There are no plans to disclose publicly the exact composition of this mixture at any time in the future.

5-11-95

Procters.Gamble

- 4. Measures for protection of the compositional information include "need to know" internal restriction within the Company. An internal code is used to protect the identity of the material. Information is maintained in locked files. Employees leaving the Company are contractually bound not to disclose Company secrets.
- 5. The exact composition of this mixture has not appeared in advertising or promotional literature, MSD sheets, any publications or any other media available to the general public or competitors.
- 6. Disclosure of the information claimed as CBI would result in substantial harm to the Company's competitive position. This formula provides an important commercial opportunity for a competitor. Knowledge of the exact composition of this mixture could enable a competitor to duplicate the formula without R&D cost, thus providing an unfair competitive disadvantage to the Procter & Gamble Company. Development of this formula required many technically trained personnel, hundreds of hours of research and development, and significant capital investment valued in aggregate at

 Any competitor would normally be required to make a similar investment to duplicate the formula. Disclosure of this information would allow a competitor to duplicate the formula without incurring significant R&D costs, thus doing substantial harm to our competitive position.
- 7. The information we have identified as confidential is not health or safety data. Any questions concerning this submission, may be directed to me at (513) 627-5551.

Sincerely,

THE PROCTER AND GAMBLE COMPANY

Richard H. Hall, Ph.D.

Manager

Regulatory'& Government Affairs
The Procter & Gamble Company

Procter&Gamble

Attachment I

Public Display Copy

Sodium alkyl benzene sulfonate

Potassium pyrophosphate

Substituted ethanol

Sodium alkyl benzene sulfonate

Substituted alkyl amide,

Sodium salt

Colorant

Fragrance

Substituted phenol

wate:

confident 7320-34-5

confident

1

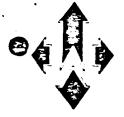
11 confident

Unknown

1)

confident

1201-27807



WIL RESEARCH LABORATORIES, INC.

Project Number: WIL-28005 Client: The Procter & Gamble Company Doc. Req. No.: CA-STR 141 134

Acute Oral Toxicity Study in Albino Rats with K0316.01

RECEIVED BY

DEC 7 1982

OPERATIONS SECTION

3154 EXON AVENUE

CINCINNATI, OH:O 45241

(513) 563-8060

Acute Oral Toxicity Study in Albino Rats with K0316.01

Introductions

A sample identified as Spic & Span L.C., 341C27R, K0316.01, was received from The Procter & Gamble Company, Miami Valley Laboratories, Cincinnati, Ohio, Inc., for the purpose of conducting acute toxicity studies. A glass jar containing the green liquid was received on September 19, 1982. The test material and container weighed 1417.3 grams and was stored at room temperature in a locked test compound cabinet.

Objective:

The objective of this study was to determine the toxicity and/or LD₅₀ value of the test material following a single oral dose to albino rats. Verbal study authorization was received from The Procter & Gamble Company, Cincinnati, Ohio followed by a letter dated September 28, 1982. This study was conducted at the Cincinnati facilities of WIL Research Laboratories, Inc. This report presents the results of that investigation from the initiation date, September 20, 1982, to the termination date, September 27, 1982.

Procedure:

Experimental Animals:

Young adult albino rats of the Sprague Dawley CD® strain were employed as test animals. On September 9, 1982, the rats were received from Charles River Breeding Laboratories, Inc., Portage, Michigan and immediately placed in quarantine. They were inspected for general health and suitability as test animals. The animals were randomly placed in numbered cages (males first) using a computer generated list of random numbers. Each rat was sexed, weighed and permanently identified with an ear tag. A card affixed to each cage also served for identification.

The rats were individually housed in wire-bottomed cages suspended above the cage board that was changed three times a week. The animal room was lighted 12 hours each day and room temperature and relative humidity were checked daily. Purina Certified Rodent Chow 5002 and water were offered ad libitum, except during the 24 hour period immediately prior to oral intubation when food was withheld. Immediately after dosing, food was offered.

The rats were quarantined and acclimated to laboratory conditions for 11 days prior to initiation of the study. Animals were observed twice daily during the quarantine period. On the last day of the quarantine period (i.e. the day prior to initiation of exposure to the test material) those animals judged to be suitable test subjects were selected from the animal shipment and used for the study. Body weights were measured

and they ranged from 175.3 to 231.9 grams. (All males were within protocol specified weight range of 190-300 grams. Eight females were between 175.3 and 189.4 grams.)

Experimental Designs

This study used four dose levels of 3.2, 4.6, 6.0 and 7.4 g/kg with ten rats (5 males and 5 females) each. The dose levels were based on a pivotal dose of 6.0 g/kg, the estimated LD₅₀ value. Mortality occurred in only one of the animals and the sponsor was contacted with these results. At the request of the client the study was terminiated on day 7.

Group	Concentration	Actual Amount Dosed ml/kg	Dose Level g/kg
1	Undiluted	2.88	3.2
2	Undiluted	4.14	4.6
3	Undiluted	5.40	6.0
4	Undiluted	6.66	7.4

1 ml of test material weighed approximately 0.90 g.

Test Material Administration:

Individual dose amounts were calculated by using day 0 fasted body weights taken prior to dosing. Mean body weights ranged for males: 186.26 - 199.82 grams and for females: 171.02 - 182.68 grams. The undiluted test material was measured in a plastic disposable syringe and administered directly into the rat's stomach using a rubber catheter and tubing adapter.

Body Weights:

All animals selected for the study were weighed on days -1 (pre-fast), 0 (exposure), 6 and 7 (termination). A final body weight was taken on the one animal found dead.

Observations and Mortality:

Each group was observed closely for gross signs of systemic toxicity and mortality at frequent intervals during the day of dosing and at least twice daily thereafter for a total of 8 days. Room conditions, as well as availability of adequate food and water, were checked and any noteworthy conditions recorded.

Calculation LD₅₀

O

The WIL computer program based on the techniques of Litchfield and Wilcoxon^a would be used to calculate the LD₅₀ if adequate mortality was obtained.

alitchfield, J. J. and F. Wilcoxon, "A Simplified Method of Evaluation of Dose-Effect Experiments," J. Pharm. and Exp. Ter., 99-113 (1949).

Necropsy:

A gross accropsy was performed on the visceral and thoracic cavities of the one animal found dead. All surviving animals were sacrificed by carbon dioxide inhalation. By request of the client, no necropsy was performed on them.

Results:

Body Weight Change Data

Individual body weights, means and gains are presented in Tables 1 and 2. Mean body weights for survivors increased at 6 days and were considered within normal limits.

Observations and Mortality:

On the day of dosing, all animals were observed at 0.50, 2.0 and 4.0 hours. Signs of systemic toxicity were observed at only the 6.0 and 7.4 g/kg dose levels and first occurred from .50 to 2 hours after dosing. A summary of clinical observations by dose level is presented below. Mortality indices are presented in Table 3.

On the day of dosing elinical signs consisted of the following:

Dose Level

3.2 g/kg No significant clinical observations (all animals).

4.6 g/kg No significant clinical observations (all animals).

6.0 g/kg Slight to mild urine stains (1M and 1P).

7.4 g/kg Red material around the mouth (2M and 1F), slight lethargy (5M), slight ataxia (5M and 1F), slight to mild salivation (2M), slight urine stains (1F).

On the days following dosing clinical signs consisted of the following:

Dose Level

3.2 g/kg No significant clinical observations (all animals).

4.6 g/kg No significant clinical observations (all animals).

Slight to moderate lethargy and inactivity (5M and 5F), slight to moderate ataxia (5M and 5F), slight to mild ataxia (5M), red moderate ataxia (5M and 5F), slight to mild ataxia (5M), red moderate ataxia (1M) and decreased defecation (1F). All males appeared normal by day 4 and all females by day 3.

7.4 g/kg Slight to moderate lethargy and inactivity (5M and 5F), slight to moderate ataxia (5M and 1F), dried red material around the nose, chin and on forepaws (1M), decreased defecation (3M and 4F), no defecation (2M and 1F) and slight to moderate urine stains (3M and 3F). All males appeared normal by day 5 and all females by day 3. One female (3081) was found dead on day 2.

Calculation of LD50:

As mortality occurred only occurred in in one of the animals at the 7.4 g/kg dose level the LD₅₀ could not be calculated. Instead a general statement was provided that the LD₅₀ was greater than the highest level dosed. Summary:

When K0316.01 was administered orally at four dose levels of 3.2, 4.6, 6.0, and 7.4, g/kg undiluted to four groups of ten albino rats (5 male and 5 female) each, signs of systemic toxicity were observed at only the 6.0 and 7.4 g/kg dose levels. These signs consisted of the following clinical observations: lethargy, inactivity, ataxia, urine stains, decreased feces and red material around the nose, chin, mouth and/or forepaws (6.0 and 7.4 g/kg), salivation, no defecation (7.4 g/kg), and death in one female (7.4 g/kg).

The incidence severity and duration of reactions was directly related to dose levels. Males and females appeared similarly affected. Survivors appeared normal on days 0 to 5: on day 0 (males and females at 3.2 and 4.6 g/kg dose levels); on day 3 (females at 6.0 and 7.4 g/kg); on day 4 (males at 6.0 g/kg) and on day 5 (males at 7.4 g/kg). Body weights increased at 6 days and were considered within normal limits.

One death occurred at the 7.4 g/kg dose level (1F on day 2). A gross necropsy conducted on this female revealed: stomach contained clear fluid and postmortem autolysis was present. A gross necropsy was not performed on the surviving animals per client request.

From the data presented (1F/10 at 7.4 g/kg dose level) the LD_{50} of K0316.01 was determined to be greater than 7.4 g/kg.

Michael Briggs A.S., Technician

12/3/82 Date

Acute Oral Toxicity Study in Albino Rats with K0316.01

Quality Assurance Unit Statement

Dates of Inspection(s)

Date(s) Findings Reported to Management and Study Director

September 20, 1982

September 24, 1982

December 1, 1982

December 3, 1982

This study was inspected in accordance with the Good Laboratory Practice Regulations, the Standard Operating Procedures of WIL Research Laboratories, Inc. The study was conducted in compliance with the Good Laboratory Practice regulations, the Standard Operating Procedures of WIL Research Laboratories and the sponsor's protocol. To the best of the signatory's knowledge there were no significant deviations from the Good Laboratory Practice regulations which affected the quality or integrity of the study. Quality Assurance findings, derived from the inspection(s) during the conduct of the study and from the inspection of the final report, are documented and have been made available to the study director and to the test facility management.

The raw data and a copy of the final report will be kept in the archives at WIL Research Laboratories, Inc.

Jacquiya McChesney, B.A. Supervisor Quality Assurance Unit

12-3-82 Date

												•					
•	11:22 01-NOV-82 FAGE 1 DAY -1											-			•		
	ACUTE ORAL TOXICITY (LDSO VALUE IN RATS) WITH ND 316.01 Implyingle body weights (G) raw rata summary			30794 223.7	483= 218.1	488= 191.2	211.760	12.575	5.624	••							
1 JAKE	ORAL TOXICITY (LDSO V IMFIVIDITAL BODY WEIG	3 HALE	477= 198.3	474= 228.4 425= 214.4	489= 220.1	3076# 208.8	214,040	11.385	5.091	•				-			
	ACUTE	. 2			467= 218.5		. 225.090	4.921	2.201	5						-	
	PROJECT NO.1911-28045 SPONSORIFRACTER & GAMME SPONTOR AO.1CA-STR 141		459= 218.7		460m 220.0		212,169	14,329	90+08	6							
\$	PKOJECT N SPINSOKIF SPONTOK N	FIDSE GROUPS					nEsn	ချို့ တွင်	; ;	E .							
								-	6-								

FEBURE FOLIUIT-20005 SFONSOR: FROCIEK & GANE SFONSON NO. ICA-SIM 141	raject po.;UIL-28005 Sporsor:Procept & Gamue Sporsor mo.!Ca-518 141		ACUTE	ORAL TOXII INDIVITU	TARLE 1 CITY (LIFSO V AL BODY WEI	VALUE IN RA SHTS (6) RA	TARLE 1 ACUTE ORAL TOXICITY (LI'50 VALUE IN RATS) WITH ND 316.01 Indiviñual body Weights (G) raw inta summary	11122 01-MOV-82 FAGE 2 DAY -1
HÜĞÊ OKOUP!	-		2		3 E M A L E	+	8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8	2 3 4
	877= 183,6 876= 218,0	863 *	196.2 175.3	491= 896=	199.9	494± 500±	209.5	
		49.5=		3067		3072	189.4	
	8765 897.8 870s (6).8	3070	385.3	3058	191.5	3080	211.9	
æ	197.200		95.350		88.840		•	
5.0.	13.036		13.508		9.296	•	12.266	
u.	5.830		1,0.4		3.710		5.486	
	ĸ7		٠,		~ >		•	

PAGE 1	**************************************			-	
ACUTE DRAL TOXICITY (LDSO VALUE IN RAIS) WITH ND 316.01 INDIVITUDAL BOOT WETGHTS (6) RAW DATA SUMMARY		3077= 182.0 3079= 196.4 478= 194.0 483= 190.5 488= 168.4	186.2A0 11.378 5.088 \$		
TABLE : DRAL TOXICITY (LDSO INDIVITUTAL BOIT WEI	3 A A L E	477± 180.1 474= 201.4 475= 192.7 489= 194.5 3076= 182.8	190,300 8,759 3,917 5		
ACUII	2	468= 197,6 465= 201,4 468= 202,4 457= 197,2 473= 205,5	199.820 2.313 1.035	٠	
F RO MET 100 FWIL - 28095 SFOW ON FFRONTER 1 GAMBLE SFOWSOR 10 FCA-STR 141		459= 195.2 392= 122.9 461= 185.4 460= 195.4 462= 193.8	180,500 2,618 4,315 5		
F KE METT SPECIONAL SPONSOR	FIGE Grouf:		5.5. 5.6. 7.6.5. 7.6.5.		·

•	FAGE 2 DAY 0	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0					
	TARLE 1 ACUTE ORAL TOXICITY (LDSO VALUE IN KATS) WITH KD 316.01 Indivinaal Bout Weights (G) ray Inta Sumary	+	494= 189.4 500= 128.7 3072= 170.2 3080= 170.0 3081= 190.7	177.800 11,207 5,012 5			•
•	TARLE 1 ORAL TOXICITY (LDSO V INDIVIDUAL BODY WEIG	FEMALE	471= 181.7 894= 161.3 3047= 148.4 3048= 172.7 3071= 170.8	171.020 7.370 3.296 5			
	ACUTE	2	862* 185.5 863* 161.9 405* 178.1 3070* 193.2 493* 183.3	180.400 11.681 5.224 5	·		
6	PROJECT 110.; IMIL-28005 SPINSORIFFICER 1 GARBLE SPÜNSOR 110.; CA-STR 141	105£ 640Ur!	9.72 189.4 876= 199.2 865= 187.0 980= 177.1 860= 189.7	HG44 182,680 5.5, 11,214 5.6, 5,015 H 5			

_	PAGE 1 DAY 6		8 10 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0				•			
	TABLE 1 ACUTE OFAL TOYICITY (LGSO VALUE IN RATS) WITH NÊ 316.01 IMBIVIOUAL BODY WEIGHIS (G) KAW DATA SUMMARY	+	3077= 240.6	3079= 255.6 478= 247.9	483= 255.9 488= 232.4		245.480	4.120	6/A)	-
	TABLE I OPAL TOXICITY (LDSO VA IMPIUTOUAL BORY WEIGH	3 4 4 6	477= 237.8	475= 255.6	189= 253,2 3076= 253.9	VOL 130	09/14/5	5,652	1	
	ACUTE	۲,	468= 287.3	466= 261.0	467= 255.5 473= 272.7	040.040	12.195	5.454	80	·
	TROJECT NO.1UII -28065 SPENJORIFROCIER & GANGLE SFONSÓR NO.1CA-STR 141		459= 271.8 190= 231.4	451= 245.7	452= 275,9 452= 275,1	256.580	16.530	7.393	S	
9	TRAJECT NO SPORTAR SFOWSGR ID	1.0.43 3.041			-	hEi.	-d:-;-	5.6.	2	
							-	-10	-	

			•			
TO JECT MO. FORDORFEKO FORSÓK MO.	FIDJETT ROJJULE-29005 SEVEDRIFAGETER I GANKLE SEVESKR HOJJCH-SIK 141	ACUTI	TABLE 1 E ORAL TOXICITY (LDSO V INBLYIDUAL BODY WETG	TABLE 1 ACUTE ORAL TOXICITY (LDSO VALUE IN RATS) WITH KD 316.01 Influtual body Wetchts (G) ray Iata sumhary		PAGE 2 DAY 6
1.002 80006.1		2	FEMALE	-		
		•	491= 220.3	230.9	# 6 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	
	8.5* 235.6	853= 187.9 496= 208.7	896= 199.7 3067= 197.7	500* 201.2 3072* 208.4		
			30.58* 207.6			
			3071* 213.1			
ME SAL	218.40	214,360	207,590	207.975		
<u>.</u>	16.297	17.632	9,380	16.865		
. ټ	7.288	7,885	4.195	8.432		
2 2.	L)	1 -7	<i>y</i>	•		

6			•		
FROJECT NO.:VIL-20005 STURGORIFROCTER & GAMRE STORGAR NO.:CA.STR. 141	-20005 1 GANKE STR 141	ALUTE. OR.	TABLE 1 11. TUXICITY (LDSO VAL) RDIVIMAL. ROIN IN.LGHT	TABLE 1 FYGJECT HD.:VIL-2009S ACUTE GRAL TOXICITY (LDSO VALUE IN RATS) WITH KD 316.01 FAGE 1 Stokenskifkjöler 1 gammee hande sikmaky data sikmaky data sikmaky data sikmaky data sikmaky	FAGE 1
השכב פעמתנו	-	~~	3 NALE	JOSE GROUP: 1 2 3 4	
HEAN G.D. S.E.	000.0	0.00°0 000°0 000°0	000.0	HEAN 0.000 0.000 0.000 5.0, 0.000 0.000 0.000 5.E, 0.000 0.000 0.000 8.E, 0.000 0.000	

·· -					· -			
PAGE 2				-				
٠								
(D 316.0) Wart								
TABLE 1 ACUTE GRAL INXICITY (1.650 VALUC IN RATS) WITH KD 314.01 INDIVIDUAL BRIPY WEIGHTS (G) RAN DATA SINKARY		3081= 177.4	0.000	_				
J O VALUE IN EIGHTS (G)		3081						
TABLE 1 NXICITY (LIDSO V DUML BORY WELG	F E # A L E		00000	0				
UTE ORAL TA								
3	~		0.000	•	·			
FRDECT NO.: WIL-28005 SFORSOR FROCTER & GAME E SPORSOR NO.: CA-STR 141			0.000	•				
JECT NO. 147 ISOR 1FROCTI ISOR NO. 1CA	LIUSE GROUP!		#5.8 5.8 5.5 5.5					

FAGE 1	• • • • • • • • • • • • • • • • • • •		
		157.320 177.800 207.975	
		188.849 157.320 171.020 177.800 207.680 207.975	
rD 316.01	EMALE 2	195.350 190.400 214.360	
KATS) WITH OF MEANS	165K FRALE 3 4	1AY -1 199,200 195,350 DAY 0 182,680 190,430 UAY 6 218,460 214,340	
TAKLE 1 ALUC IN SUMMARY	- =	IAY -1! DAY 0! IAY 6!	_
TABLE 1 FRO JECT NO LULL-2005 ACUTE ORAL TOXICITY (LDSO VALUC IN KATS) WITH PD 316.01 FROND SKIFKGCTER 1 GANKLE BODY LEIGHT (G) SUMHARY OF MEANS SKONSON NO LICA-STR 141	1 SEX 1 100SE GRI	212.150 225.080 214.040 211.720 [NAY -1 199.200 195.350 188.849 157.320 185.580 199.820 190.330 186.260 DAY 6! 182.680 190.430 171.020 177.800 254.580 289.040 254.780 245.480 DAY 6! 218.460 214.360 207.680 207.975	1- 1 2- 2 3- 3 4- 4
ACUTE ORAL T	-	211.760 186.260 245.480	-
щ	m	214,040 190,300 254,780	2
JIL-2005 TER 1 GANS 24-5TR 141	1 2 3 4	225.080 199.820 269.040	2-
FROJECT NO. IUIL-20005 SPONSORIFROCTER 1 GANGLE SPONSON NO. ICA-STR 141	1 A H - 1	212.150 188.580 254.560	

	PAGE 1	DAY -1 TO 6											
	IN RATS! WITH KD 316.01	G) RAW DATA SUMMARY	BJEE	-	31,2	3079= 31.9				4 * 4 * 5 * 6 * 6 * 6 * 6 * 6 * 6 * 6 * 6 * 6	4.225	1.809	v o
TAME 2	ACUTE ORAL TOXICITY (LDSO VALUE IN RATS) WITH KD 316.01	INDIVITUAL BODY WEIGHT GAINS (G) RAW D.TA SUMMARY	NALE	-	39.5	474= 45.0	41.0	33.1	45.1	40.740	4.928	2.204	so.
	ACUTE 0			~		455= 42.2				43.950	13.229	5.916	NO.
•	FROJECT NO.:WIL-28005	SFONSORIFROCIER & GANRLE SFONSOR NO. 1CA-STR 141			±69±	392= 46.2				44,420	7.820	3.497	¥n
	FKOJECT !	SPONSOK SE SPONSOR IN		LIGSE GROUP:						riEAN	5.0	5,6,	*

FROJECT NO.1WIL-29005 SFONSOKTFROCTER I GAIRLE SFONSOK NO.1CA-STM 141	2 E 7	·	ACUTE	OKAL TOXIC	TABLE 2 ITY (LPSO V) ODY WEIGHT (ALUE IN RAT BAINS (G) F	TARLE 2 ACUTE ORAL TOXICITY (LGSO VALUE IN RAIS) WITH NI 314.01 INDIVITURAL BODY WEIGHT GAINS (G) RAW DATA SUMMARY		PAGE -1 10	F1 79
NOSE GROUF:			~		3 HALE 4	7	9 1 4 5 5 5 5 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6	B		
677# 2	23.6 17.6	862* 863*	19.8 12.6	491=	20.4 22.7	494s	71.4			
	8.63	*96 *	17.5	30672	11.2	3072*	19.2			
	₩.	493*	22.1	3071	23.8					
19,	260		9.000		18.640		4,300			
.80	429		4.167		5.192		8,349			
J.	3,783		1.864		2,322	-	4.175			
	J									

			ACUTE OF	AL 10X1C	77 (LISO V	ALUE IN RA	IS) #ITH KD 316.01		FACE	_
FUNCOFFRÜCTER 1 GAMBLE FONSOR NO.:CA-STR 141	7E _			VI FAUAL : BO	EV VETGHT	GATUS (Ĉ) 1	INDIVIDUAL BOUY JEIGHT GAINS (G) RAU (ATA SUMAARY	Y	0 10	~ 0
noch neurole		•		-	HALE	-	HALE			_
-		•		•		-				į
	•	-89	87.7	477=	57.7	3077	58.6			
	 	4553	67.3	174:	72.0	3079=	59.2			
	=	456=	59.8	4753	65.9	#B/+	53.9			
£5 +09 +	57.5	± 29 Þ	58.3	180	58.7	483=	₩9.4			
	<u></u>	473=	7.2	3976	71.1	488	64.0		-	
	900		9.220	9	4.480					
5.0. 10.3	25.	_	2.634		6.750		3.638			
4.631	153		5.762		3.019		1.627			
	5 7		v٦		.		יטע			

0

316.01 Hary			
ACUTE OKAL TOXICITY (LDSO VALUE IN RATS) WITH ND 314-01 INDIVIDUAL BODY WEIGHT GAINS (0) RAW DATA SUMMARY	FEMALE 4	491* 38.4 494* 41.5 894* 38.4 500* 32.5 3047* 29.1 3072* 33.4 3048* 34.9 3080* 21.2	36.660 33.400 4.971 8.949 2.223 4.475 5
ACUTE OKAL Ingivi	2	842= 30.5 83= 26.0 496= 30.6 307= 41.1 493= 41.6	33.960 7.000 3.130 5
FROVECT HOLIUIL-18005 Sportorikacter i Gaare Sportorialistr 141	indse Group;	872= 37.8 876= 36.4 865= 47.4 880= 21.8 850= 35.5	35,790 5,0, 9,152 5,E, 4,093 N 5

TABLE 3

Acute Oral Toxicity Study in Albino Rats with K0316.01

Mortality Indices

Dose Level		D	ays	· ·	Died/
g/kg	0	1	2	3	Tested
3.2 M	0	0	٥	0	8/5 -
3.2 M	0	0	0	0	0/5
4.6 M	0	8	0	0	0/5
4.6 F	0	0	0	•	0/5
6.0 M	. 0	0	0	0	0/5
6.0 P	0	0	0	0	0/5
7.4 M	0	0	0	0	0/5
7.4 F	0	0	1	0	1/5

Triage of 8(e) Submissions

Date sent to triage:			NO	N-CAP	Ć	AP	
Submission number: _	13387A		TSC	CA Inventory;	Y	N	(B)
Study type (circle app	ropriate):					<i></i>	
Group 1 - Dick Cleme	ents (1 copy tota	1)					
ECO	AQUATO						
Group 2 - Ernie Falke	e (1 copy total)			•			
ATOX	SBTOX	SEN	W/NEUB				
Group 3 - Elizabeth M	Margosches (1 co	opy each)					
STOX	стох	EPI	RTOX	GTOX			
STOX/ONCO	CTOX/ONCO	IMMUNO	СҮТО	NEUR			
Other (FATE, EXPO, Motes: THIS IS THE ORIGI					DATAB	ASE E	NTRY
		For Contrac	tor Use Only				
entire documen	nt: 0 1 2	pages //	2	pages			
Contractor revi	ewer:)	Date:	: 1/24/96			_

WOLUNTARY ACTIONS MED STUDIES PLANNED TO THE PROPERTY OF WHERE ROLLING TO WHERE ROLLING TO THE PROPERTY OF THAT THE PRODUCTION DESCONTINUED DESCONTINUED DESCONTINUED DESCONTINUED DESCONTINUED DESCONTINUED DESCONTINUED	### F. F. C. BRAILED (ANSWAL) BRAILED (ANSWAL) CLASTO (BY VITRO) CL	
SECRETARION REQUESTED. FLAY DATE. SO INTO METO METOTESTED SO INTO REQUESTED (TECH) SO INTO REQUESTED (VOL. ACTIONS) SO INTO REQUESTED (VOL. ACTIONS) SO INTO REQUESTED (VOL. ACTIONS) SO INTO REGULESTED (VOL. ACTIONS) SO INTO REGULESTED (VOL. ACTIONS) SO INTO REGULESTED (VOL. ACTIONS) CONTROL CONTROL	CONTRAL) FOR THE SECOND SECON	
Company Company Sin Date 08 20 92 Sin Date 08 92 Sin Date 0	MAS) (GR VITRO) (GR VITRO) (TO (STRAM) (TO (STRAM) (TOX (ASSAUL) (TOX (T	THE PARTIES NO. (CONTINUE)

CECATSITRIAGE TRACKING DBASE ENTRY FORM

Procters.Gamble

Attachment I

Public Display Copy

Sodium alkyl benzene sulfonate

Potassium pyrophosphate

Substituted (ethanol)

Sodium alkyl benzene sulfonate

Substituted alkyl amide,

Sodium salt

Colorant

Fragrance

Substituted phenol

Mates

confident 7320-34-5

confident

11

confident

unknown 11

L

Acute oral toxicity is of low concern based on the following mortality and corresponding doses (mg/kg) in rats: 0/10 (3200, 4600, 6000) and 1/10 (7400). Clinical signs included lethargy, hypoactivity, and ataxia (\geq 6000).